PCT

(30) Priority data:

(GB)

9207120.8

612.455.3801

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5:		(11) International Publication Number:	WO 93/19671
A61B 5/14	A1	(43) International Publication Date:	14 October 1993 (14.10.93)

GB

(21) International Application Number: PCT/GB93/00650

30 March 1993 (30.03,93) (22) International Filing Date:

1 April 1992 (01.04.92)

(71) Applicant (for all designated States except US): OWEN MUMFORD LIMITED [GB/GB]; Brook Hill, Wood-stock, Oxford OX20 ITU (GB).

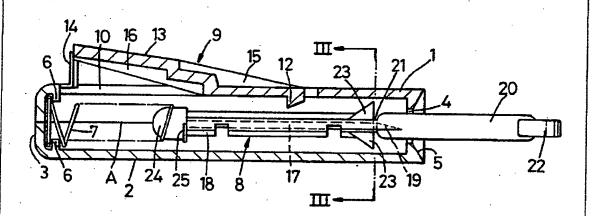
(72) Inventors; and (75) Inventors/Applicants (for US only): MARSHALL, Jeremy [GB/GB]; 16 Cranham Street, Jericho, Oxford OX2 6DD (GB). CROSSMAN, David, Danvers [GB/GB]; The Tower, Christmas Common, Oxford OX9 5HL (74) Agents: LAINE, Simon, James et al.; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL50 1JJ (GB).

(81) Designated States: AU, BR, CA, JP, KR, RU, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

(54) Title: BLOOD SAMPLING DEVICE



(57) Abstract

A blood sampling device has a tubular body (1, 2) housing a spring loaded (7) lancet (8) whose needle (17) is initially protected by a cap (20) which projects out from the forward end of the body. A rocker-like trigger (9) is formed as part of the moulded body (1, 2) and holds the lancet (8) in a retracted position when the lancet is pushed back by the projecting cap (20). The cap can then be removed by a twist and pull action, breaking it free from the lancet body, which is prevented from rotating. Pressure on the trigger (9) releases the lancet (8), which is shot forward by the spring (7) for momentary projection of the needle tip (19), and then retracts to bring the needle tip within the body.

_9319671A1_J_>

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

			•		
AT	Atistria	FR	France	MR	Mauritagla
AU	Australia	GA	Gabon	MW	Maluwi
BB	Borbados	GB	United Kingdom	NL.	Netherlands
BE	Belgium .	GN	Guinoa	NO:	Norway
BF	Burkina Paso	GR	Greece	• N2	New Zealand
BC ·	Bulgaria	HU	Hungary	PL	Poland
BJ	Busin	1E	treland	PT	Portuggi
BR	Brazil	IT .	Italy	RO	Romania
· CA	Conada	JP.	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	ទេប	Suden
CG	Congo		of Korca	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SK	Slovak Republic
CI	Côte d'Ivolne	KZ	Kazakhstan	SN	Senegal
CM.	Capuroon	LI	Llechtenstein	SU	Soviet Union
CS.	Cembusiowakia -	LK	Sri Lanka	TD	Chud
cz	Czech Republic	LU	Luxembourg	TG	Togo
DΕ	Germany	MC	Моласо	UA	Ukraine
DK	Dusmark	MG	Madagascar	US	United States of America
ES	Spain	ML.	Mali	VN	Viet Nam
E21	Mark A	***	1.4 P	•	

PCT/GB93/00650

٦

Blood sampling device

This invention relates to blood sampling devices, and in particular to a pricker to draw a small drop of blood for analysis. Such prickers are widely used by diabetics, for example, who need to know their sugar level. However, there are many other applications.

These days, with AIDS, there is widespread concern surrounding the use of needles and their part in transmitting disease. Once a needle has been used on an infected person, subsequent use or an accidental prick on another could be fatal.

There is therefore a growing demand for a pricker which can be used just once and, having been used, is automatic-ally rendered safe for carriage and disposal.

Several such prickers have been proposed, for example in EP-A-0427406 and EP-A-0433050. These work well, and use a lancet which has been in production for many years. However, it is important for disposable objects with a very transient life to be made as simply and cheaply as possible, without compromising on effectiveness. This the present invention aims to do.

According to the present invention there is provided a disposable pricker comprising an elongate body with a spring-loaded lancet carried therein, the lancet tip normally being within the body, a trigger mechanism to retain the lancet in a fully retracted position energising the spring means and actuable to release the lancet to cause

25

02/19/2008 14:16

WO 93/19671

10

15

20

25

PCT/GB93/00650

2

the tip to have a momentary position projecting from the forward end of the body, and an elongate cap encasing the lancet tip and having a head external of the body, the cap providing means to retract the lancet and being breakable free of the lancet to leave the tip exposed.

Conveniently, the trigger mechanism comprises a rocker with an outwardly projecting portion for manual operation and an inwardly projecting portion for co-operation with the lancet. The rocker may be centrally connected to the main part of the body by small webs which are distortable to allow the rocker action.

It has been found beneficial for the rocker to have further means connecting it to the body to resist pivoting below a predetermined actuating force. This prevents accidental operation.

Preferably the trigger mechanism is formed integrally with the body, which will generally be moulded in plastics material with a certain resilience. As the lancet is pushed back to prime the device, a projection on it can snap past an inwardly projecting lug on one end of the trigger and this will temporarily hold the lancet retracted. Pressure on the other end of the trigger will raise the lug clear and release the lancet.

Although the body and trigger will preferably be integral, they may initially be moulded as two main parts, one of which contains the trigger, connected by a thin flexible web, presenting the body in an opened out condition. When the lancet and spring means are in place, these

10

612.455.3801

PCT/GB93/00650

3

two parts will be folded together and secured, as by adhesive or ultrasonic welding.

In order to assist in breaking the cap away from the lancet, the latter may have an engagement with the interior of the body that prevents it rotating about its longitudinal axis, at least when the lancet is retracted. The cap may therefore be twisted off by one hand with the other holding the body.

Another characteristic of the fit of the lancet within the body is preferably that, once the lancet has been fired, it should tend to lie skew to the axis of the body. This would make it difficult, using the twisted off cap for example, to insert it again and press the lancet back for possible re-use.

For a better understanding of the invention, one embodiment will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a longitudinal section of a blood sampling pricker,

Figure 2 is a plan view of the pricker of Figure 1, and

Figure 3 is a cross-section on the line III-III of Figure 1.

The body of the pricker is of generally square tubular form and is of moulded plastics construction. Two channel-like parts 1 and 2 are closed together and secured in a plane A to form the tube, which is closed at the rear end 3 and which has an opening 4 at the forward end. An external

10

15

20

25

02/19/2008 14:16

PCT/GB93/00650

HSML, P.C. (acp)

bevel 5 around this opening forms a shallow recess into which a thumb or finger, for example, can be pressed for pricking.

The parts 1 and 2 have interior lugs 6 opposing each other close to the rear end 3 to provide a trap for one end of a coil spring 7 by which a lancet 8, to be described in more detail below, is made captive. Otherwise, the lower part 2 is plain. However, the upper part 1 has a trigger 9 integrally moulded with it. The trigger lies largely within a bottle shaped aperture 10, the head of the bottle pointing forwards, and in plan view the trigger 9 is similarly shaped but smaller. Its main connection to the part 1 is by short bridges or webs 11 at the shoulders of the "bottle" and in the normal, relaxed state, the pricker adopts the position shown in Figure 1. In that case, the forward end of the trigger, in front of the webs 11, is generally flush with the interior of the upper part of the body 1, but at its leading end a hook 12 projects down into the body cavity. The hook 12 has a shallow slope facing forwards and a steep rear face. To the rear of the webs 11, the pricker 9 steps upwardly to a thumb pad 13 by which it can be pivoted, and there are two optional thin L-shaped strips 14 connecting the rear corners of this pad 13 to the main part 1 of the When the pad 13 is pressed, these strips 14 (if provided) buckle or shear off at their connection to the rear end 3 and the trigger pivots to move the hook 12 out clear of the interior of the body 1. Longitudinal reinforcing ribs 15 and 16 make the trigger 9 an effectively rigid

02/19/2008 14:16

PCT/GB93/00650

5

rocker.

The strips 14 are not necessary if the device is to be provided with the lancet 8 as shown in Figures 1 and 2 and as described below, when it has to be cocked by the user before release. But there is also a call for precocked devices and then there is a need to prevent premature actuation of the trigger, as by careless handling for example. The strips 14 perform this safety function, since they demand a very positive pressure on the pad 13. They will generally buckle or shear suddenly, giving a quick action of the trigger and clean release of the lancet. A pre-cocked lancet will still usually have a cap, as described below, to maintain sterility of the needle.

The lancet 8 comprises a steel needle 17 almost entirely encased in a cruciform-section jacket 18, except for its tip 19. Initially, this tip is concealed within the rear end of an elongated cap 20 joined to the jacket 18 by a weak collar 21. The cap 20 passes freely through the aperture 4 and terminates outside the body 1 in a tab 22.

Just to the rear of the collar 21, the jacket 18 terminates at its forward end in two opposed wedges 23, their sloping sides facing rearwardly and being convergent, while their forward sides are co-planar and at right angles to the axis of the needle 17. Viewed end-on, as in Figure 3, the wedges 23 form a rectangle slightly smaller than the inner cross-sectional profile of the body 1,2. At the rear end, the jacket is formed with a domed stud 24 with an undercut slot 25 to locate and trap the forward end of the

20

25

10

15

20

25

612.455.3801

PCT/GB93/00650

٠6

coil spring 6, which fits over the stud 24.

Initially, the pricker is as shown in Figure 1, with the cap 20 projecting well beyond the forward end of the body 1, 2 but with the tip 19 of the needle still inside the body and encased by the rear end of the cap 20. prime or cock the trigger, the cap is simply pressed axially towards the body I causing the lancet to compress the spring 7. As one of the wedges 23 reaches the hook 12, the sloping surfaces co-operate to rock the trigger 9 until the wedge 23 snaps past the hook 12, whereupon the resilience of the webs 11 and the strips 14 restores the trigger back to the Figure 1 position to trap the lancet in a fully retracted position. The tab 22 is then grasped and, with the body 1 held, is given a twist. The wedges 23 prevent the lancet rotating within the body 1, and so the weak collar 21 is sheared. The cap 20 can then be withdrawn. A thumb or finger is pressed into the aperture 4 and the pad 13 is pressed releasing the lancet. It shoots forward to make the prick and, the spring 7 momentarily having been over extended, draws the lancet back a little so that the tip 19 ends up safely inside the body 1,2.

Although the leading end of the lancet does not have much freedom of movement within the body 1,2 its rear end can shift up and down. The lancet will therefore tend to come to rest slightly skew to the axis of the body 1,2. Certainly, if an attempt is made to retract the lancet again by inserting something through the hole 4, the spring 7 and the lancet will tend to go out of alignment. This makes it

02/19/2008 14:16

PCT/GB93/00650

HSML, P.C. (acp)

very difficult to use the discarded cap to poke the lancet back for possible re-use. Thus, the pricker and cap will have to be discarded.

10

15

20

612,455,3801

PCT/GB93/00650

PAGE 37/41

CLAIMS

- A disposable pricker comprising an elongate body with a spring-loaded lancet carried therein, the lancet tip normally being within the body, a trigger mechanism to retain the lancet in a fully retracted position energising the spring means and actuable to release the lancet to cause the tip to have a momentary position projecting from the forward end of the body, and an elongate cap encasing the lancet tip and having a head external of the body, the cap providing means to retract the lancet and being breakable free of the lancet to leave the tip exposed.
- 2. A disposable pricker as claimed in Claim 1, wherein the trigger mechanism comprises a rocker with an outstanding projecting portion for manual operation and an inwardly projecting portion for co-operation with the lancet.
- A disposable pricker as claimed in Claim 2, wherein the rocker is centrally connected to the main part of the body by webs which are distortable to allow the rocker action.
- 4. A disposable pricker as claimed in Claim 3, wherein the rocker has further means connecting it to the body to resist pivoting below a predetermined actuating force.
- 25 5. A disposable pricker as claimed in any preceding claim, wherein the trigger mechanism is formed integrally with the body, which is of moulded plastics material.

10

15

02/19/2008 14:16

PCT/GB93/00650

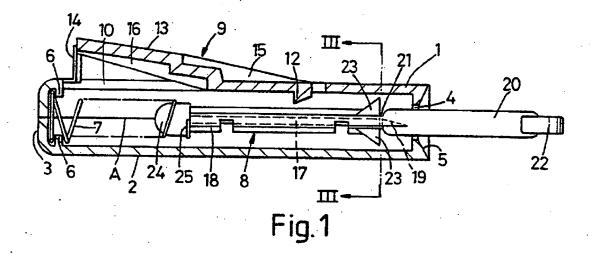
9

HSML, P.C. (acp)

- 6. A disposable pricker as claimed in any preceding claim, wherein the lancet has a detent and the trigger has a co-operative lug, projecting inwardly with respect to the body, the detent being arranged to snap past the lug as the lancet is retracted and to hold the lancet in that position.
- 7. A disposable pricker as claimed in any preceding claim, wherein the body is moulded in two parts connected by a thin flexible web, presenting the body in an opened out condition but closeable together when the lancet and spring means are in place.
- 8. A disposable pricker as claimed in any preceding claim, wherein the lancet has an engagement with the interior of the body preventing it rotating about its longitudinal axis at least when the lancet is retracted.
- 9. A disposable pricker as claimed in any preceding claim, wherein the fit of the lancet within the body is such that, once the lancet has been fired, it will lie skew to the axis of the body.

612.455.3801

PCT/GB93/00650



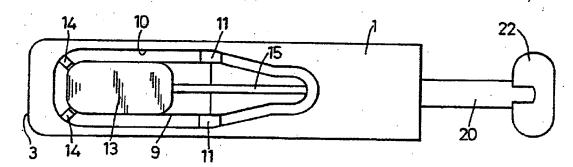


Fig. 2

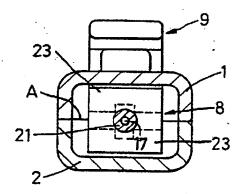


Fig. 3

02/19/2008 14:16

INTERNATIONAL SEARCH REPORT

International Application rec

PCT/GB 93/00650

L CLASSIF	ICATION OF SUBJ	ECT MATTER (If several classification	symbols apply, indicate all) ⁶	
According t	to International Paten	t Classification (IPC) or to both National (Classification and IPC	
Int.C1.	5 A61B5/14		•	•
		,	•	•
IL FELDS	SEARCHED			
	· · · · · · · · · · · · · · · · · · ·	Minimum Docum	entation Searched?	
Classificati	on System		Classification Symbols	
Int.Cl.	5	A61B		
	· ·····	Documentation Searches other	than Minimum Documention	
	•	to the Extent that such Documents		•

			•	i
III. DOCUM	ENTS CONSIDERE	D TO BE RELEVANT		
Category *	Citation of Do	coment, if with indication, where appropri	iale, of the relevant passages 12	Relevant to Claim No.13
	······································			
X]	EP,A,D 4	127 406 (OWEN MUMFORD,	LTD.)	1-3,5,6,
1	15 May 1			8
	cited in	the application		
	266 CO1	umn 4, line 6 - line 25 umn 5, line 29 - column) . E lima E	
		in 10; figures 9,11,12	o, the s	
Y	EP,A,O 4	33 050 (OWEN MUMFORD,	LTD.)	1,5
•	19 June	1991	•	1 - 1
.		the application		
A .	see colu	mn 2, line 54 - column	3, line 2	6-8
	see colu	mn 3, line 42 - line 5	s; figure 1	
Y	EP.A.0 4	58 451 (BOEHRINGER MAN	NHETH CORP)	1,5
•	27 Novem	ber 1991	-	1,5
A	see colu	mn 2, line 41 - column	4, line 15	2-4
		mn 7, line 19 - line 3	0	
	see Tigu	res 1-4,8,9		
· 1	•		/	
ľ	• .		-,	'
		•		
* Special c	exegories of cited doc	omena: 10	"I" inter specument published after the inter	national filino date
"A". docum	ment defining the gene	eral state of the art which & not	or printity date and not in conflict with cited to understand the principle or ther	the application but
E exile	dered to be of purifical redocument but public	ar retevation hed on or after the international	invention	
trimg	SECO	doubts on priority claim(s) or	"X" document of particular relevance; the ch cannot be considered novel or cusnot be involve an inventive step	considered to
Which	is cited to establish to m or other special rea	be publication date of another	"Y" document of particular relevance; the ci-	
"O" docum		rai disclosure, use, exhibition or	decoment is combined with one or more	other such docu-
P docum	eent published prior to	the international filing date but	ments, such combination being obvious in the arc.	to a person skilled
ister	than the priority date	dalmed	"&" document member of the same patent fa	mily
V. CERTIFIC	CATION			
Date of the Ac	tual Completion of the	e International Search	Dute of Malling of this International Sec	urch Report
	الال 20	LY 1993		-
			1 3 -07- 1993	
aterestional S	carching Authority		Signature of Authorized Officer	
	EUROPEAI	N PATENT OFFICE	RIEB K.D.	
			1	

International Application No

PCT/GB 93/00650

IIL DOCUME	International Application No MENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)					
Category o	Citation of Document, with indication, where appropriate, of the reterant passages	Relevant to Claim No.				
A	US,A,4 539 988 (G.R. SHIRLEY ET AL.) 10 September 1985 see column 3, line 7 - line 15 see column 4, line 54 - line 58	1-8				
A	see figures 7,9 EP,A,O 255 338 (GLYME VALLEY TECHNOLOGY) 3 February 1988 see figure 6D	9				
	FR,A,771 890 (L. RIEDMÜLLER) 18 October 1934 see page 2, line 83 - line 93; figures 1,2	1,2,4				
						
		•				
• •						
		•				
	ritre shoul) (Jamery 1983)					